STA
Single Tooth Anesthesia System®

Featuring the Wand® STA Handpiece

MILESTONE SCIENTIFIC®

STA-5110 100-120 volts
STA-5220 200-240 volts

CE 0459

Caution: Federal law restricts this device to sale by or on the order of a dentist or physician.

MEDICAL USE:

This device is intended for use only in subcutaneous or intramuscular injections of local anesthetic agents for dental applications. It should not be used for intravascular (IV) or other routes of administration. This device should be used only by practitioners who are familiar with, and observe applicable labeling regarding the use of local anesthetic agents for dental applications.

The STA (Single Tooth Anesthesia) System senses real time relative interstitial pressures at the tip of the needle.

The STA (Single Tooth Anesthesia) System facilitates the targeting of the intraligamentary space.

Milestone Customer Care

If there are any questions or you need assistance, please call us immediately toll-free at:

USA **Milestone Scientific**
220 South Orange Avenue
Livingston, NJ 07039
1-800-862-1125

EC REP

MDS Ltd.
Nottingham, UK
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CONTENTS

INTRODUCTION

Introduction to STA (Single Tooth Anesthesia) System® featuring the Wand® STA handpiece

Congratulations on purchasing your new **STA** (Single Tooth Anesthesia) computer controlled local anesthetic delivery system (CCLADS). The STA (Single Tooth anesthesia) System is a state of the art device which facilitates a wide variety of anesthetic injections, including palatals and STA-Intraligamentary Injections, consistently and comfortably to your patients.

The **STA** (Single Tooth Anesthesia) System is the only local anesthetic delivery system that incorporates Dynamic Pressure Sensing Technology® (DPS). DPS technology is a revolutionary technology developed by Milestone Scientific Inc. that allows dental professionals to perform successful single tooth anesthesia techniques using the STA-Intraligamentary Injection. This technique is detailed within the manual.

Please take the time to familiarize yourself with the **STA** (Single Tooth Anesthesia) System by reading the manual. You should also practice a few injections at the "bench" to familiarize yourself with the system.

We hope that your new STA (Single Tooth Anesthesia) System provides many years of successful service to you and to your patients. If you have any questions or comments, please call Milestone Scientific Inc. at 1-800-862-1125.

READ THE FOLLOWING CONTENTS OF THIS MANUAL BEFORE USING THE SYSTEM.

THE WAND® STA IS INDICATED FOR USE ONLY UNDER THE DIRECTION OF TRAINED MEDICAL PROFESSIONALS.

NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED.

INSTALL THE INSTRUMENT ON A FLAT AND SECURE SURFACE. LAYOUT THE INSTRUMENT TO AVOID TRIPPING HAZARDS OR PULLING ON A POWER CORD, FOOT PEDAL OR ANY TUBING.

DO NOT PLACE THE WAND® STA SYSTEM IN A POSITION WHERE IT MIGHT FALL AND HARM THE PATIENT OR DAMAGE THE DEVICE.

THE INSTRUMENT SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT. IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED

PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN AFFECT THE OPERATION OF THE WAND® STA INSTRUMENT. REFER TO RECOMMENDED SEPARATION DISTANCES IN MANUAL INSERT LS-0053.

AN ITEM LABELED FOR SINGLE-PATIENT USE REQUIRES THAT THE ITEM BE DISCARDED BETWEEN PATIENTS.

FEATURES

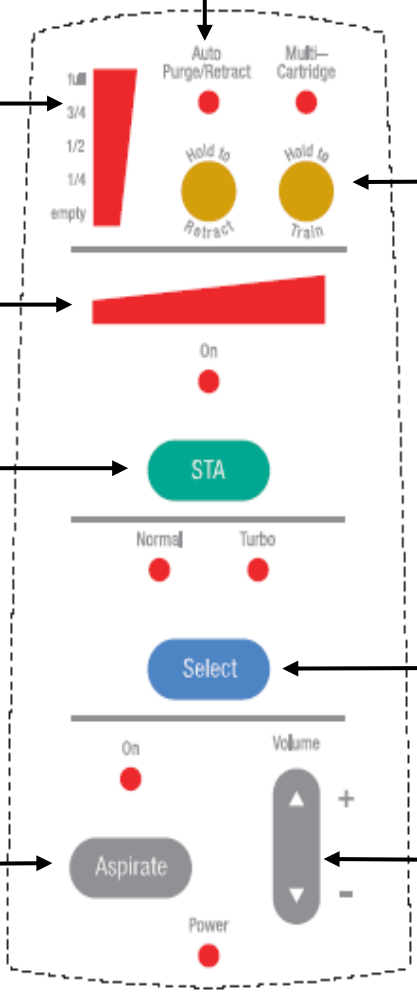
Auto Purge/Retract
Controls AutoPurge function, Hold to retract plunger

Cartridge Volume Indicator
Shows amount of anesthetic remaining

Pressure Indicator

STA Button
Activates and Deactivates Single Tooth Anesthesia mode with Dynamic Pressure Sensing technology

Aspirate
Turns aspiration function On/Off



Multi-cartridge
Controls Multi-cartridge function.
Hold to Train, activates Training mode.

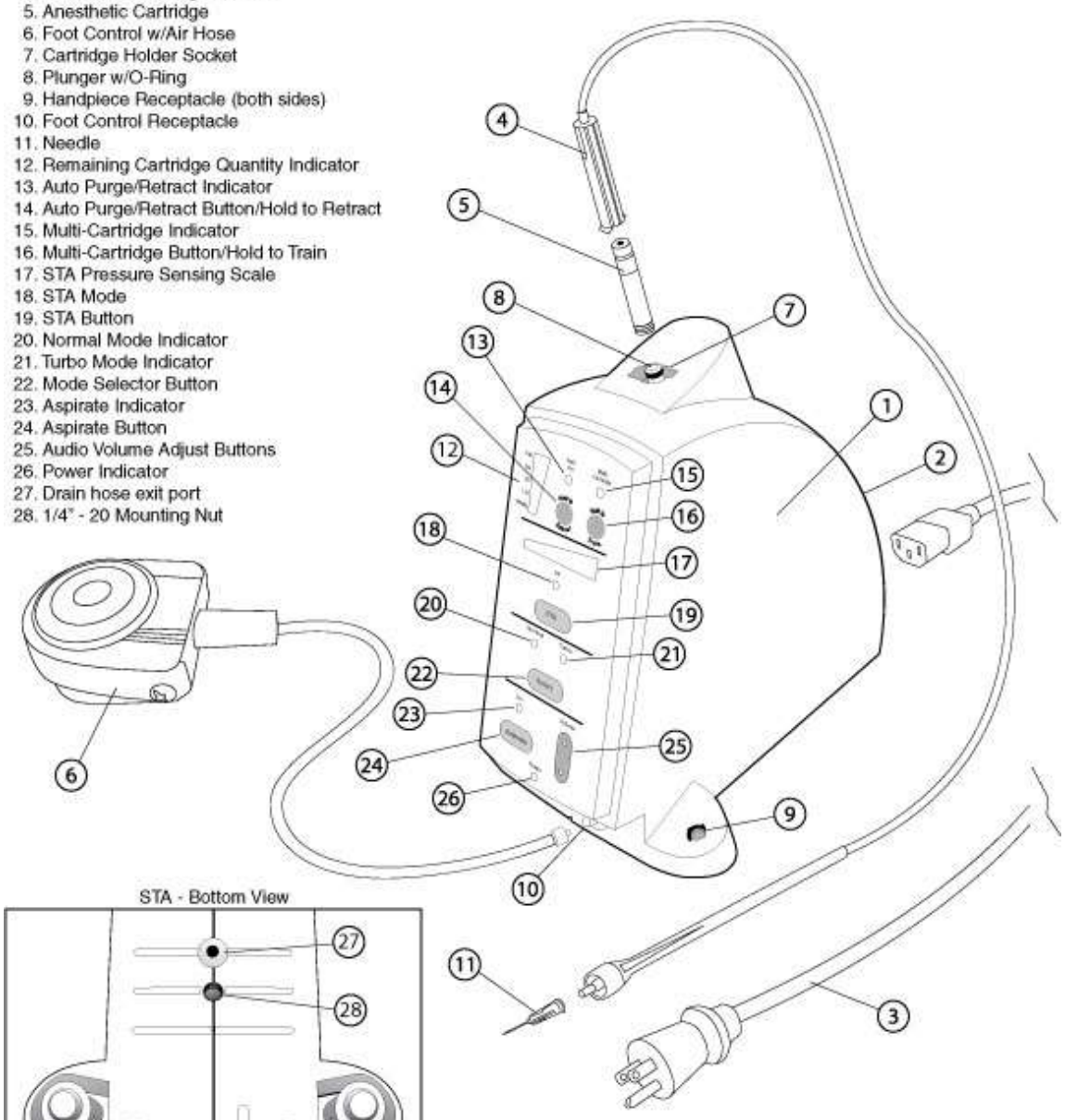
Select Button
Activates either Normal mode with 2 speeds or Turbo mode with 3 speeds

Volume
Controls all audible Volume in the device

FEATURES

STA Single Tooth Anesthesia System

1. Drive Unit
2. Power Switch (@ back of drive unit)
3. Power Cord (US version shown)
4. Anesthetic Cartridge Holder
5. Anesthetic Cartridge
6. Foot Control w/Air Hose
7. Cartridge Holder Socket
8. Plunger w/O-Ring
9. Handpiece Receptacle (both sides)
10. Foot Control Receptacle
11. Needle
12. Remaining Cartridge Quantity Indicator
13. Auto Purge/Retract Indicator
14. Auto Purge/Retract Button/Hold to Retract
15. Multi-Cartridge Indicator
16. Multi-Cartridge Button/Hold to Train
17. STA Pressure Sensing Scale
18. STA Mode
19. STA Button
20. Normal Mode Indicator
21. Turbo Mode Indicator
22. Mode Selector Button
23. Aspirate Indicator
24. Aspirate Button
25. Audio Volume Adjust Buttons
26. Power Indicator
27. Drain hose exit port
28. 1/4" - 20 Mounting Nut



STA - Bottom View

BASIC OPERATION

OPERATION
Set Up

Connect foot control (WA-1043) hose to front outlet on drive instrument. Hand-tighten snugly.

Position drive instrument on a flat, level surface within 91.44 cm (3 feet) of patient. (The **Wand® STA** hand-piece micro tubing is 152.4 cm (5 feet) long from the drive instrument to the handpiece.)

Plug the drive instrument electrical power cord (WA-1050 for 100-120V instruments, and WA-1055 for 200-240V instruments) into the back of the instrument and then to a power outlet. Place the STA (Single Tooth Anesthesia) System and power cord in an accessible location such that in case of emergency, the instrument may be powered down or unplugged quickly.

Warning: Do not use an extension cord to connect the STA (Single Tooth Anesthesia) system. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

Note: Do not place STA (Single Tooth Anesthesia) System within 30.48 cm (12 inches) of other electrical devices such as electro-surgery instruments as they may cause interference.

Warning: There may be possible safety hazards associated with the external radiofrequency interference (RFI) or electromagnetic radiation which may affect the safe operation of this device and therefore should be avoided.

Power 'On/Off'

Press power switch on the back of the drive instrument to turn system power 'On' and 'Off'. Plunger will automatically retract to 'down' position when instrument is turned 'On'. When first turned on the STA (Single Tooth Anesthesia) System set to the default modes. The STA (Single Tooth anesthesia) System will self-calibrate in 5 seconds, having no effect on the user.

Wand ® STA Handpieces

The Wand® STA hand-piece is safety engineered with sharps protection to aid in the prevention of needlesticks. Specific instructions for each version of the handpiece are provided in the following sections.

Note: Only use handpieces and other components with the STA (Single Tooth Anesthesia) System that are manufactured or recommended by Milestone Scientific. The Wand® STA hand-piece provided without needles will accept a wide variety of single use hypodermic needles with a plastic Luer lock fitting. The decision to use a specific needle compatible with the Wand® STA hand-piece is at the sole discretion of the dental professional to use the needle that will best meet the needs of the patient for the procedure being performed.

BASIC OPERATION

Wand® STA handpiece

Product Description

The Wand® STA handpiece is shaped to allow a pen-type grasp for accurate needle insertions. However, the handpiece can be broken to create a short, easily controlled needle handle for injections into tight areas. (See illustration)

Fig. 1

The Wand® STA handpiece is available with a selection of needles that are pre-attached and bonded to the handpiece:

- Wand® STA handpiece without needle (REF: STA-5050A)
- Wand® STA handpiece With 30 G x ½" needle (REF: STA-5050-305)
- Wand® STA handpiece With 27 G x 1 ¼" needle (REF: STA-5050-2725)
- Wand® STA handpiece With 30 G x 1" needle (REF: STA-5050-301)
- SAFETY Wand® STA handpiece Without needle (REF: STA-5040ASAF)
- SAFETY Wand® STA handpiece With 30Gx½" needle (REF: STA-5040 SAF-305)
- SAFETY Wand® STA handpiece With 27Gx1¼" needle(REF:STA-5040 SAF-2725)
- SAFETY Wand® STA handpiece With 30Gx1" needle (REF: STA-5040 SAF-301)

OPERATION:

Familiarize yourself with the operation of the STA (Single Tooth Anesthesia) System by practicing with the device prior to clinical use.

1. Turn drive instrument on.

2. Remove a needle from the sterile packaging. Maintain sterility.

3. Hold the Wand® STA handpiece firmly. Place the needle into the open end of the handpiece and rotate needle. It is critical that the needle is firmly secured to the handpiece.

Note: The handpiece equipped with the 30 gauge 1.27cm (30 gauge ½ inch) needle is optimized for the STA-Intraligamentary injections. Contact your dealer for availability.

4. After the needle is attached to the handpiece, place the needle cap into wand holder on either side of the STA (Single Tooth Anesthesia) System.

5. Slide the diaphragm end of cartridge (with metal band) into cartridge holder, push cartridge firmly and completely into the holder until you feel the spike penetrate the rubber diaphragm.

6. Place open, flange end of cartridge holder into the cartridge holder socket on top of the instrument, and rotate counter-clockwise 1/4 turn.

7. After attaching the cartridge holder to the drive instrument, the STA (Single Tooth Anesthesia) System will automatically purge the air from the tubing and needle. The handpiece is now primed and ready for use.

Note: Do not turn the instrument "on" or "off" if an anesthetic cartridge is installed. This will result in damage to the instrument.

Warning: The flow rate during the prime/bolus cycle is 0.0691 ml/second. The maximum pressure warning is disabled during the priming (i.e., purge) phase. The alarm is re-enabled immediately following this operation.

Note: If you experience difficulty puncturing a cartridge it may be due to variations in the rubber diaphragm material. Try these four solutions to correct the situation:

- Place the cartridge into the holder; gently rotate the cartridge stopper 360 degrees against the spike two or three times. Then press firmly into the holder, puncturing the cartridge. A slight twisting motion as you press may also help puncture the cartridge.

- Place cartridge into cartridge holder. Place cartridge against a firm surface or counter top and press quickly and firmly down.

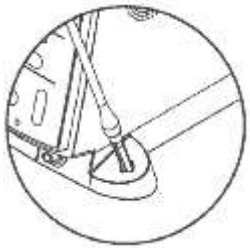
- Swab rubber diaphragm with alcohol which acts as a lubricant.

- Place the cartridge into the holder. Press firmly against spike, stretching the rubber diaphragm for 5-6 seconds. Release and immediately re-push rapidly and firmly against the spike.

BASIC OPERATION

One Handed Needle Recapping Technique

1. After the needle is attached to the handpiece, place the needle cap into wand holder on either side of the STA (Single Tooth Anesthesia) System.

Fig. 2 

2. Hold needle cap firmly with one hand, remove the needle from the cap with the other hand by pulling straight out from the cap. Do not twist. (Cap remains in receptacle on the side of the instrument).
3. Between injections, lightly set the needle back into the cap. Do not press into the cap. This is a temporary holding dock for the needle.
4. When ready to use the handpiece and needle, simply remove the handpiece and needle from the cap. Return the needle to the cap when not in use.
5. When the procedure is completed, firmly press the needle into the cap on the side of STA (Single Tooth Anesthesia) System, locking the cap back on the needle. When locked in place and keeping your hands behind needle point remove the cap with the attached needle from the instrument and discard in an approved manner.

Note: Recap needle ONLY
1.) When medically necessary.
2.) When no other alternative exists.
3.) In accord with all applicable governmental and local laws and regulations.

BASIC OPERATION

WARNINGS:

Single Use ONLY: 

The Wand® STA handpiece is gamma sterilized. The Wand® STA handpiece and tubing assembly, as with any syringe, opens a fluid pathway directly to the patient. **This device is for single use only. It must not be re-sterilized** and must not be used on successive patients or the same patient at a later visit. Reusing The Wand® STA handpiece places the patient at risk. The anesthetic cartridge must not be reused on multiple patients.

STERILE, unless individual plastic package is opened or damaged. If package is opened or damaged, do not use and dispose of per applicable local regulations.

Disposal:
Used Wand® STA handpieces should be considered medical waste after use and must be disposed of per applicable local and Federal regulations.

Instrument must be returned to Milestone Scientific for proper disposal in accordance with WEEE Directive 1999/31/EC.

Do not use deformed or damaged needle:
Deformed or damaged needles may interfere with the proper operation of the Wand® STA handpiece

Lubricate the "O" Ring and Plunger:

A properly maintained and lubricated 'O' Ring is necessary for effective functioning of the system. The following procedure is recommended:

a. Check 'O' Ring for cracks, deterioration, or lack of lubrication daily
b. If cracked or deteriorated, replace at once.
c. If dry, lubricate with silicon gel. While plunger is extended, lightly lubricate plunger shaft with silicon gel. This will enhance smooth performance.

Replacement "O" Ring reorder #: WA-1030

CAUTIONS:

- Federal law restricts this device to sale by or on the order of a physician or dentist.
- Maintain sterile conditions.

BASIC OPERATION

Additional Important Information

STA (Single Tooth Anesthesia) System introduces a revolutionary technology to local anesthesia injections called Dynamic Pressure Sensing (**DPS**) Technology. It is important that the operator fully understand several aspects of DPS technology to make the most of this exciting new breakthrough. The STA (Single Tooth Anesthesia) System with DPS technology provides the operator with **continuous real-time pressure feedback** throughout the injection process. This will be a new experience for the practitioner and it is important to understand many new clinical implications of having continuous feedback. It is analogous to using a highly accurate "apex locator" in that the technology allows one to make subtle clinical adjustments resulting in a difference between clinical success and failure. The STA (Single Tooth Anesthesia) System is a powerful technological clinical tool when used correctly.

IMPORTANT: It is common that when performing the STA-Intraligamentary injection (described starting on page 21) **that the operator may move the needle to several different locations to identify the optimal needle-to-ligament position based on DPS feedback.** This "searching" method validates how DPS with real-time feedback provides critical information to the user. With all other injection devices the operator is unaware if a correct needle position has been established, typically using the first location.

IMPORTANT: It is common that when performing the STA-Intraligamentary injection that the operator will encounter an "Over-Pressure" condition. An Over-Pressure condition is when the maximum pressure of the instrument has been reached and the instrument will sound a warning and stop. This is typically as a result of either a clogged needle tip or excessive hand-pressure being applied to the hand-piece blocking anesthetic flow. With either of these situations the needle must be removed and the injection restarted. The ability to accurately and consistently detect needle blockage using the STA (Single Tooth Anesthesia) System validates the critical importance of this technology to the clinician.

Auto-Calibration:

IMPORTANT: When the STA (Single Tooth Anesthesia) System is first turned "On" the instrument will perform an auto-calibration of the system, during the initial 5 seconds. During this time Do Not install a cartridge holder onto the drive instrument. Note: periodically during use the instrument will perform auto-calibration; this has no effect on operation.

BASIC OPERATION

Basic Modes of Operation

The STA (Single Tooth Anesthesia) System is equipped with three basic modes of operation. They are:

1. STA mode, which has a single anesthetic injection flow rate. This mode is activated when the instrument is turned on.
2. Normal mode, which has 2 anesthetic injection flow rates.
3. Turbo mode, which has 3 anesthetic injection flow rates.

The user may change between modes during any procedure and the selection is retained while cartridges are replaced. When the STA (Single Tooth Anesthesia) System is turned off and then back on, the default setting is the STA mode.

STA Mode: Provides the user with real-time Dynamic Pressure Sensing (DPS) technology while injecting using the *ControlFlo* rate. Aspiration default is set to “ON” and can be changed by the user.

Normal Mode: In this mode the system has two flow rates, *ControlFlo* and *RapidFlo*. The DPS (See section on DPS technology) pressure sensing technology is not activated. Aspiration is set to “On” and can be changed to “Off” by the user.

Turbo Mode: The Turbo mode provides the user with an additional speed, *TurboFlo*; all three speeds are controlled by the foot-control pedal. Aspiration is set to “On” and can be changed to “Off” by the user.

BASIC OPERATION

Foot Control Operation

The foot control supplied with the STA (Single Tooth Anesthesia) System is an air activated switch. Slight pressure = *ControlFlo* (1 cc per 207 seconds). Modest pressure = *RapidFlo* (1 cc per 35 seconds). When selected, additional pressure engages *TurboFlo*. The *TurboFlo* (1 cc per 17 seconds) delivers the anesthetic solution 2 times faster than *RapidFlo* and must be used with extreme care. (All published flow rates are +/- 15%)

Warning: *ControlFlo* is the only rate that should be used when performing Palatal and STA-Intraligamentary injections. ***RapidFlo*** **and *TurboFlo* should never be used for these injections as they can result in pain and tissue damage.**

IMPORTANT: *ControlFlo* should be used at the beginning of **ALL** injection techniques. It provides a controlled and safe administration that normally results in little or no discomfort. Once initial "numbness" has occurred you may decide to switch to a more rapid rate, i.e. *RapidFlo* or *TurboFlo* during infiltration injections and Inferior Alveolar block injections. Typically ¼ of the cartridge should be administered using the *ControlFlo* rate before switching to a more rapid rate of delivery.

TurboFlo is intended to be used only after initial anesthesia (numbing) has occurred for the Inferior Alveolar Nerve Block Injection or a Supraperiosteal Infiltration Injection. The oral tissues that are affected by these injections are composed of loose, elastic tissues that can accommodate this rapid rate: however, caution should always be used, and operator judgment is critical to performing a safe and effective injection.

Always be certain that the foot control hose is firmly attached to the instrument. **Any air leaks will degrade the operation.** Practice using the foot control to become comfortable with the operation and pressure required to activate the various delivery rates.

BASIC OPERATION

Cruise Control Function

This feature allows the operator to engage the *ControlFlo* without continuously depressing the foot control. This feature is available in the Normal, Turbo and the STA settings.

To use Cruise Control:

1. Begin *ControlFlo*. Listen to beeps.
2. After 3 beeps a voice will say CRUISE. This opens a 5 second window during which you can activate the cruise control.
3. Immediately remove foot from foot control. Cruise control is engaged and a voice will say SET.

Note: You will not hear the word SET spoken in the STA Mode when cruise control is engaged.

4. If you do not want to engage cruise control, do not remove foot from foot control during this window.
5. To disengage cruise control, depress foot control and release or press firmly for faster speeds.

BASIC OPERATION

Manual Purge and AutoPurge

Prior to making any injection, all of the air should be “purged” from the microtubing and from the needle.

AutoPurge Operation

The STA (Single Tooth Anesthesia) System can automatically purge with the AutoPurge feature. When enabled, each time a new cartridge is attached to the drive instrument the plunger automatically advances, moving the anesthetic through the tubing to purge the air from the system. A small amount of anesthetic can be observed at the end of the needle following a successful purge. The instrument is preset at the factory to use AutoPurge as the default.

To Use AutoPurge

1. Load and attach a cartridge holder to the drive instrument, twisting it ¼ turn counter-clockwise.
2. The plunger will automatically advance. This will expel the air from the tubing and from the needle. A small droplet of anesthetic at the tip of the needle indicates a successful purging.
3. The Anesthetic Solution Volume Gauge will now be illuminated to FULL, indicating the instrument is ready to use.

Manual Purge Operation

If the operator desires not to use the AutoPurge, it can be turned off, activating the manual purge function. To manually purge the system, press the AutoPurge button, indicator light is now turned off and the air is NOT automatically purged from the tubing. Depress the foot pedal at which time the drive instrument automatically extends the plunger a preset distance to purge air from the micro tubing and the needle.

BASIC OPERATION

Multi-Cartridge Feature

This function is useful when a second or third cartridge is required during a single procedure using the same disposable Wand® STA handpiece and there is no need to purge air from the handpiece and tubing as it was previously purged. This operation will save unnecessary loss of anesthetic solution when using more than one cartridge.

1. While the STA (Single Tooth Anesthesia) System plunger is completely retracted, press the Multi-Cartridge button. Indicator light will illuminate ON.
2. Remove the empty cartridge and replace with a new full cartridge. Insert cartridge holder onto instrument. (The device will NOT purge itself).
3 Continue injection.
4. STA (Single Tooth anesthesia) System will default back to Multi-Cartridge OFF mode following the end of the injection. The Multi-cartridge mode will turn off automatically after 60 seconds if a new cartridge is not attached to the drive instrument.

BASIC OPERATION

Plunger Operation

When the STA (Single Tooth Anesthesia) System is first turned on, the plunger retracts and parks in the retracted position. Inserting the cartridge automatically engages the plunger and purges the tubing. The system is ready when the indicator is illuminated, showing a FULL volume.

As the plunger is extended dispensing anesthetic, the volume indicator light will show the amount of anesthetic solution remaining in the cartridge. As the plunger is fully extended, an audible warning beep is sounded. This indicates that the cartridge is empty. When the cartridge is fully emptied or when the cartridge holder is removed, the plunger will automatically retract into the drive instrument. If the Auto-Purge/Retract is not set, the plunger can be retracted by pressing the Hold to Retract button.

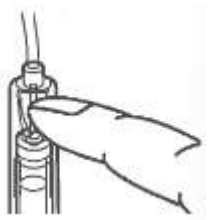
Plunger Retraction

Retraction of the plunger can be performed using any of the following three methods:

1. When the “Auto-Purge/Retract” feature is activated (noted by the illuminated green LED on the front panel) the plunger will automatically retract when the cartridge holder is removed from atop of the STA (Single tooth Anesthesia) drive instrument.
2. Manual retraction of the plunger. When the “Auto-Purge/Retract” feature is not activated it is necessary to manually retract the plunger during use. This is accomplished by depressing the multipurpose “Hold to Retract” button for greater than 4 seconds.
3. Retraction of the plunger to the return “home” position will occur after the plunger has fully expressed the content of an anesthetic cartridge. (This will occur irrespective of the “AutoPurge/Retract” feature state and does not require the removal of the cartridge holder from the STA (Single Tooth Anesthesia) drive instrument.)

NOTE: To turn the “Auto-Purge/Retract” feature “On” and “Off” use the multipurpose “Hold to Retract” button. You may toggle it “On/Off” by depressing and releasing the button for less then 4 seconds.

Removal of Cartridge

Ensure plunger is fully retracted. Remove the cartridge holder from the cartridge socket drive instrument by rotating cartridge holder clockwise 1/4 turn. Remove used cartridge by pushing with finger placed into slots in side of holder. If continuing injection procedure, remove and discard the used cartridge and insert a new full cartridge into the cartridge holder and continue.	

BASIC OPERATION

Aspiration

1. **IMPORTANT ASPIRATION PRETEST**
   It is recommended that an aspiration pretest be performed prior to any injection requiring aspiration. This simple pretest will confirm that the disposable handpiece, anesthetic cartridge and attached needle are free from air leaks which might compromise aspiration efficiency.

   Once the drive instrument purge cycle is completed, orient the needle horizontally with the bevel down or to the side. Pretest will not work if needle bevel is in the up position.

   Express anesthetic extra-orally at the *ControlFlo*™ rate (slow speed). Release the foot control and observe the drop of anesthetic at the end of the needle. If a drop is retracted and returns to the needle tip at the end of the aspiration cycle, in about 5 seconds, aspiration is functioning properly.

   If droplet does not retract, do the following in the order listed:
   i. Re-tighten needle hub and retest
   ii. Replace cartridge and retest
   iii. Replace the Wand® STA handpiece and retest
   iv. Lubricate O-Ring and retest
   v. Replace O-Ring and retest

   This test should be repeated with each new anesthetic cartridge when aspiration is to be used. Rubber stopper movement in the cartridge can also be monitored during aspiration as a further assurance.

2. Aspiration “On/Off” feature: Aspiration can be performed automatically when the Aspiration feature is set to the “On” position (indicated by the green LED light on the front panel). When this feature is set to the “On” aspiration state, aspiration can be performed in all three modes (STA, Normal & Turbo). To change the setting before or during a procedure, press the “Aspirate” button on the front of the control panel.

3. TO ASPIRATE: Be sure aspiration mode is activated (light on). Aspiration is initiated by lifting your foot from the foot control in STA, Normal or Turbo mode. If in cruise control, tap the foot control to activate. When the aspiration function occurs, the plunger is retracted a preset distance, then automatically returns to its original position. Positive aspiration will show blood in the needle hub and/or tubing contained in the handpiece.

BASIC OPERATION

Audible Signals and Audio Volume control.

Your new STA (Single Tooth Anesthesia) System is equipped with a number of audible indicators that monitor speed of anesthetic delivery, and status of how much anesthetic has been delivered. While using the STA feature, it provides an audible feedback to identify the correct position of the needle within the periodontal ligament tissues to successfully perform a STA-Intraligamentary injection.

The device has a system-wide VOLUME control, whereby the audio volume may be controlled. Press to either increase or decrease the overall audio volume of the device. This change will be retained for future use. The audible sounds cannot be fully turned off. Ensure audio is functioning properly prior to beginning the injection.

Cartridge Volume Gauge and Audible Cartridge Tone Indicator

The STA (Single Tooth Anesthesia) drive instrument monitors the amount of anesthetic used by visual and audible indicators. The front panel of the drive instrument has LED indicators which light up showing the amount of anesthetic solution remaining. The instrument will also “bong” once when ¼ cartridge is expressed, twice when half is expressed and three times when ¾ is used. Empty is indicated by a double “chirping” sound. (Cartridge volume indications are +/- 0.1 ml)

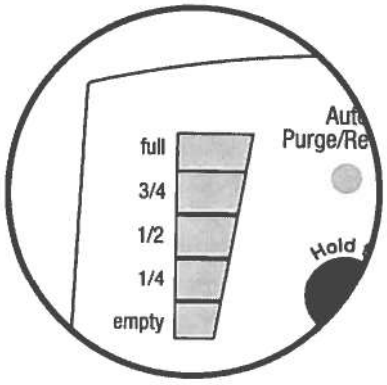


Fig. 12

BASIC OPERATION

Dynamic Pressure Sensing (DPS™) Technology

The STA (Single Tooth Anesthesia) System is equipped with an innovative DPS Technology which provides the user with “Real-Time” feedback of the actual pressures read at the tip of the needle during an anesthetic injection. The real time pressure is read many times per second and shown on the pressure sensing gauge. Clinical research has shown that successful intraligamentary injections are associated with relatively high injection pressures. The DPS technology provides the user with a feedback mechanism to indicate these higher pressures and thus guide the proper placement of the needle tip. The DPS Technology is only activated in the STA mode.

STA-Intraligamentary Injection

The STA (Single Tooth Anesthesia) System provides DPS™ technology that is capable of identifying specific tissues during the dental injection. The STA mode allows the practitioner to accurately identify the periodontal ligament tissue. It also enables the clinician to maintain the correct needle position within the periodontal ligament when performing the newly described STA-Intraligamentary Injection. Developed by Dr. Mark Hochman, the STA-Intraligamentary Injection represents a new concept in local dental anesthesia techniques.

Developed by Dr. Mark Hochman, the STA-Intraligamentary injection represents a new concept in local anesthesia techniques. The STA (Single Tooth Anesthesia) System is the only anesthesia system that provides clinicians with the 3 critical elements of information when performing a STA-Intraligamentary Injection:

1. It guides the clinician to position the needle tip to the periodontal ligament.
2. It provides ongoing feedback that ensures the needle has not moved during the procedure.
3. It alerts the dentist if there is a needle blockage or any leakage in the system.

BASIC OPERATION

Performing the STA-Intraligamentary Injection

1. Turn the STA (Single Tooth Anesthesia) drive instrument to “On”. The system will default to the STA mode.
2. Load and attach the Wand® STA bonded handpiece with the pre-attached bonded 30 gauge 1.27cm (30 gauge ½ inch) needle and the appropriate anesthetic. The instrument will automatically purge the air from the system. Rest the handpiece in the cap holder.
3. While holding the Wand® STA handpiece in a pen-like grasp, place the needle into the gingival sulcus of the tooth to be anesthetized. Simultaneously, activate the *ControlFlo*® rate by depressing the foot control. It is important to gently and slowly advance the needle within the sulcus, as if it were a periodontal probe. It is highly recommended that the clinician use a finger rest to control and stabilize needle movements.
4. The STA (Single Tooth Anesthesia) System provides a continuous audible and visual feedback to guide the needle tip to the periodontal ligament. As the foot control is depressed, the device will begin sensing. The user will then hear the word “Cruise” at which time the cruise control function can be engaged by removing one’s foot from the pedal. If the operator’s foot is removed from the foot control within 4 seconds of hearing the spoken word “Cruise” the instrument will engage cruise control.

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5. In the STA mode, the DPS technology provides real time pressure feedback via:
   a. The visual Pressure Sensing Scale (Gauge) comprised of a series of orange, yellow and green LED lights. The orange LED’s indicate minimal pressure, the yellow LED indicate mild pressure and the green LED’s indicate moderate pressures indicative of the periodontal ligament tissue. (The pressure scale is accurate within +/- 10% for PDL and maximum pressure and +/- 20% for intermediate pressures).
   b. The auditory Pressure Sensing Scale is composed of a series of triple ascending tones “beep, beep, beep”. Increasing pressure is indicated by the triple ascending sequence. When the periodontal ligament is identified, the user will hear the letters “PDL” spoken, followed by a series of extended tones “beeeep, beeeep” indicating correct needle positioning.

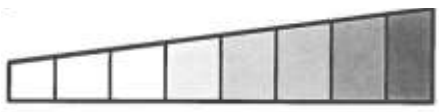


Fig. 13

Performing the STA-Intraligamentary Injection (continued)

Note: It is typically found when performing the STA-Intraligamentary injection that it is often necessary to relocate the needle tip to find the periodontal ligament tissues. The operator should not be concerned that it may take several attempts to find the optimal location. Using DPS technology, the user can be confident that the optimal location has been identified

The continuous DPS technology provides the user with important on-going information that the needle has not moved from the optimal location during the entire injection process. The DPS feedback will also alert the operator to the proper hand pressure applied to the handpiece. Excessive pressure can result in "blockage" of flow of anesthetic solution. This will be detected and result in an "over pressure" condition.

An "over-pressure" condition is when pressures exceed the maximum pressure programmed in the instrument. The maximum pressure generated by the STA (Single Tooth Anesthesia) System is 31.6 Kg/cm^2 (450 psi) +/- 10%. Pressures exceeding this will trip the occlusion warning and prevent any further administering of anesthetic. The STA (Single Tooth Anesthesia) System will sound an auditory and visual warning "RELOCATE" or "Overpressure". Do not operate this equipment if the warning has been activated for any reason. The clinician can then restart the injection and reset the warning. It might be necessary to re-position or move the needle to a new location.

Note: It is not uncommon for a "relocate" or "over-pressure" condition to occur, this emphasizes an importance of being able to monitor real-time pressure with DPS technology. This may occur as a result of excessive hand pressure on the Wand® STA handpiece. It may also result from a blockage or clogging of the needle. In either situation, the needle must be relocated. If the "relocate" or "overpressure" situation persists, remove the needle from the patient's mouth to determine if the needle is "blocked" or "clogged". If the needle is clogged it will need to be replaced prior to reuse. In the event of an occlusion, the bolus amount generated when the system is in the STA mode is 0.077 ml when the blockage is released. When a needle is replaced, press the foot pedal and observe anesthesia flowing from the needle tip before continuing the injection.

Note: Execute the following procedure in order to test the occlusion alarm.
The operator may test for a "relocate" or "over-pressure" condition by occluding a needle and using the STA mode. The pressure will build in the STA mode and the alarm will sound.

BASIC OPERATION

Based on the auditory and visual pressure sensing feed-back, it is not unusual for the operator to have to reposition the needle several times before locating the proper position of the needle within the periodontal ligament. Additionally, slight needle movements can result in rapid loss of pressure. The user will need to withdraw and reposition the needle to establish an effective periodontal ligament location.

Note: The single most common error when performing the STA-Intraligamentary injection is obtaining an overpressure condition to which the instrument will announce, "Overpressure" or "relocate". This error is caused by the operator applying too much hand pressure when holding the STA Wand handpiece, Excessive hand pressure can reduce, even block the flow of anesthetic solution producing the overpressure situation. To avoid this error, one should always use a light, delicate grasp and apply a light, gentle force when positioning the needle into the sulcus and contacting the periodontal ligament.

Removal of the needle from the ligament should be performed mid-way during the aspiration cycle to prevent a back-spray of anesthetic solution into your patient's mouth. Since the injection is performed under pressure, if the needle is otherwise removed, the patient's mouth will be sprayed with bitter tasting anesthesia. Therefore, the operator is advised to remove the needle during aspiration, i.e. when the STA (Single Tooth Anesthesia) System is retracting during aspiration.

Drug Selection:

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The following information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

When using 2% Xylocaine Hydrochloride 1:100,000 Epinephrine or other local anesthetics formulated with a 2% concentration the following recommendations are made:

- A drug volume of 0.9 ml is recommended for single rooted teeth.
- A drug volume of 1.8 ml is recommended for multi-rooted teeth.

When using 4% Articaine Hydrochloride or other local anesthetics formulated with a 4% concentration the following recommendations are made. **NOTE:** it is recommended when using 4% Articaine hydrochloride that only a 1:200,000 vasoconstrictor concentration be used:

- A drug volume of 0.5 ml is recommended for single rooted teeth.
- A drug volume of 0.9 ml is recommended for multi-rooted teeth.
- The use of 2% local anesthetics containing a vasoconstrictor concentration of 1:50,000 parts is not recommended for administration of an intraligamentary injection.
- The use of 4% local anesthetics containing a vasoconstrictor concentration of 1:100,000 parts is not recommended for administration of an intraligamentary injection or palatal injections (AMSA & P-ASA).

Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. As noted above if you elect to use 4% concentrated anesthetic drug, use ½ the normally recommended and use extreme caution.

BASIC OPERATION

Training Mode

The STA (Single Tooth Anesthesia) System comes with a unique training mode that provides additional voice prompts not found in the standard mode. It is enabled by pressing and holding the “HOLD TO TRAIN” button for 4 seconds. It is highly recommended that the Training Mode be used while the practitioner becomes familiar with the STA (Single Tooth Anesthesia) System.

1. Depress the Hold to Train button for 4 seconds and the device replies with “TRAINING MODE ON”. The button may also be held while powering up the STA instrument.
2. Load the anesthetic cartridge into the handpiece and attach the handpiece to STA instrument. The STA (Single Tooth anesthesia) instrument automatically purges the handpiece and replies with “READY”.
3. Press **STA** button and the STA (Single Tooth Anesthesia) instrument replies with “STA MODE”.
4. Depress the foot control, the STA (Single Tooth anesthesia) instrument replies “SENSING”. An audible tone indicates the device is expressing the anesthetic. After 3 beeps a voice will say “CRUISE”. This opens a 5 second window during which you can activate the cruise control. Immediately remove foot from foot control. Cruise control is engaged and a voice will say “SET”.
5. As pressure builds, the indicator lights change from orange to yellow to green, the device also says “ASCENDING” and uses a unique 3-note tone.
6. The correct injection pressure is indicated when the device repeats ”PDL” and provides the PDL slow tone.

The Training Mode is useful for all modes as the STA (Single Tooth Anesthesia) System is equipped with an audible voice that will explain the various audible indicators. This will assist the user in quickly learning the proper operation of the STA (Single Tooth Anesthesia) System. The Training Mode may be deactivated at any time at the user’s discretion.

BASIC OPERATION

Global Default Setting

The STA (Single Tooth anesthesia) instrument may be set to a global default by pressing the volume button during power-up. This sets the device to the following:

1. STA Mode is “ON” and set to tones.
2. AutoPurge/Retract is set to “ON”.
3. Aspiration is set to “ON”.
4. The device will use tones to indicate the various flow rates. .
5. The device will chime when the cartridge is empty, ¼, ½, and ¾ full.
6. The audible volume is set at the midpoint.
7. The Cruise Control is enabled.
8. The Multi-Cartridge feature is set to “OFF”.
9. The STA (Single Tooth anesthesia) will automatically notify you when to lubricate the O-ring and plunger.

Features 1-6 may also be programmed by holding down the Select button while the instrument is turned on. The Select button must be held down thorough the entire setting. When released, the feature settings changes are saved.

MAINTENANCE AND CARE

Maintenance and Care

1. Cleaning the Drive Instrument
   After each use the instrument should be disinfected. Spray disinfectant on a soft towel and wipe the instrument. Do not spray directly onto instrument. A barrier system can also be used over the drive instrument.

WARNING: Never use light oil sprays (e.g., WD40™) to clean or lubricate instrument. Use only Milestone Silicone gel lubricant provided in handpiece box.

2. "O" Ring and Plunger Maintenance and Lubrication
   A properly maintained and lubricated "O" Ring is necessary for effective functioning of the aspiration cycle. We recommend that the following procedure be initiated:
   a. Check "O" Ring for cracks, deterioration, or lack of lubrication daily.
   b. If cracked or deteriorated, replace at once.
   c. If dry or not lubricated, lubricate with silicone gel provided in handpiece box.
   d. While plunger is extended, lightly lubricate plunger shaft with silicone gel. This will enhance smooth performance.

NOTE: Instrument will automatically remind you to lubricate after every 24 cycles.

CAUTION: When Auto Purge/Retract button is pressed and held down while the power is turned 'On' the plunger will automatically fully extend. See plunger changing and sterilizing.

3. Plunger and "O" Ring Changing and Sterilizing
   Plunger and O-Ring Assembly may be removed for sterilization or replacement. **Do not activate cleaning mode with cartridge in place.**

   Removal of plunger and O-Ring assembly (Cleaning Mode)

   Remove cartridge holder from socket if present. Turn off the device, press and hold the AutoPurge/Retract button and then turn the device back on. The drive instrument will automatically extend the plunger and O-Ring assembly for removal. Unscrew the plunger from the drive instrument by rotating it counter-clockwise.

A recommended autoclave procedure is as follows:

1. Remove plunger from the STA (Single Tooth anesthesia) drive instrument.
2. Manually clean with a soft brush, taking care to remove all lubricant and debris. Remove O-Ring.
3. Rinse and dry plunger. Inspect for corrosion or other damage.
4. Place plunger in an autoclave bag and seal.
5. Sterilize using steam autoclave (moist heat steam under pressure) following manufacturer's instructions for sterilization of steel surgical instruments. Typical parameters are: Time 15-30 minutes, Temperature 121º C (250º F), pressure 1.05 Kg/cm^2 (15psi).
6. Prior to use, install new O-Ring, apply silicone lubricant, and affix plunger to the STA (Single Tooth anesthesia) drive instrument.

Installation of plunger and O-Ring assembly

Carefully slide O-Ring onto O-Ring groove at end of plunger. Screw the threaded end of the plunger into drive instrument and rotate plunger clockwise until properly secured in drive instrument. **Note: Apply a small amount of silicone lubricant to the O-Ring weekly or after every 24 cycles. Inspect O-Ring daily for signs of deterioration.**

4. Cartridge Breakage

Occasionally, a cartridge may break during insertion or operation. If a cartridge breaks it is important that all glass and fluid be removed from around the plunger and cartridge holder receptacle in the instrument. Failure to remove glass particles can cause jamming and malfunction of the plunger. Any liquid spilt in the cartridge socket holder will be safely diverted out through the bottom of the instrument.

If a cartridge breaks:

1. Remove cartridge holder and cartridge.
2. Turn instrument over and remove any glass particles or fluid.
3. Using high volume suction, or compressed air, clean out cartridge holder receptacle on top of instrument to remove fluid and glass particles.
4. Inspect for remaining glass particles and remove.
5. Remove plunger. Clean and autoclave the plunger before reuse. Discard O-Ring and replace with a new one.

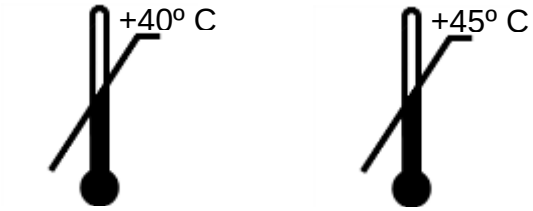
Warning: Door located on back of the instrument is for certified personnel only. It should never be opened for any reason by unauthorized individuals.

MAINTENANCE AND CARE

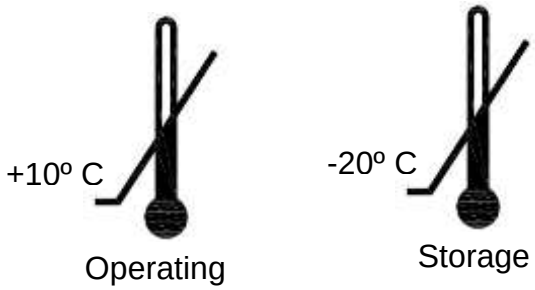
STORAGE and HANDLING

The STA (Single tooth Anesthesia) System should not be exposed to either excessive heat or cold. Place the STA (Single Tooth Anesthesia) System where it will not be subject to falling or being pulled off the shelves. In addition, the STA (Single Tooth anesthesia) System should not be splashed with liquids.

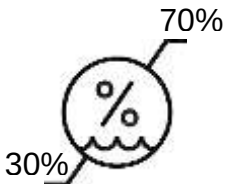
a. Operating and Storage High Temperatures (+40º C/+45º C, respectively)



b. Operating and Storage Low Temperatures (+10º C/-20º C, respectively)



c. Operating Humidity (30% to 70% non-condensing)



MAINTENANCE AND CARE

CAUTIONS FOR USE

- **NO MODIFICATION OF THIS EQUIPMENT IS ALLOWED**. There are no user-serviceable parts in the STA (Single tooth Anesthesia) System. The STA (Single tooth Anesthesia) System can only be serviced by qualified Milestone Scientific technicians.

- Do not connect any items to the STA (Single tooth Anesthesia) System that are not listed as supplies for the STA (Single tooth Anesthesia) System.

- Do not place the STA (Single tooth Anesthesia) System in a position where it might fall and harm the patient or damage the device.

- Never immerse the STA (Single tooth Anesthesia) System in water or other fluids. This system is not waterproof.

- Never use sharp objects to depress control buttons on the device. They may damage the device by rendering buttons inoperable.

- Follow your institution's procedures and applicable laws regarding the proper disposal or recycling of device components.

- Never use organic solvents (e.g., acetone), *quaternary* ammonia compounds, strong acids, or bases to clean any portion of the system.

- Never sterilize the STA (Single tooth Anesthesia) System in a steam of autoclave or gas. Using autoclave or gas sterilization can seriously damage the system and void warranty.

Warning: Failure to strictly adhere to the principles of use in this operator's manual can cause over injection or under Injection with possibility of serious injury.

TROUBLESHOOTING

SYMPTOM	CAUSE	SOLUTION
No power light	Switch is "OFF" No power at power outlet	Turn Switch to "On" Check fuse or circuit breaker
No aspirate light	Not in aspirate mode	Press reset once
When depressing foot control drive instrument stops and/or warning light flashes	Computer malfunction	1. Press and hold aspirate button for 3 seconds. 2. Turn instrument OFF, wait 15 seconds and restart. 3. Call Technical Service for assistance: 1.800.862.1125.
	Improper installation of the plunger or O-ring	Install plunger or O-Ring properly
	Dirty plunger	Remove, clean, lubricate and re-install plunger.
	Blocked needle or cartridge	Replace needle and/or disposable
Drive instrument does not respond to foot control activation	Foot control tubing is bent, pinched or blocked	Unblock foot control air hose.
	Tubing not securely attached	Retighten air hose connection.
Anesthetic not flowing properly	Check for air gap between plunger and cartridge	Replace cartridge
	Check for spike properly puncturing cartridge	Push to puncture or replace handpiece assembly. See pg. 6 for proper puncture technique.
	Blocked needle or disposable	Replace needle and/or handpiece.
Aspiration inadequate	Worn or dry O-Ring	Replace or lubricate O-Ring

TROUBLESHOOTING

SYMPTOM	CAUSE	SOLUTION
Cartridge is not pierced (does not fully seat into cartridge holder)	**Inconsistent rubber diaphragm in cartridge**	**See pg. 6 for proper puncture technique.**
Tabs break off cartridge during initial use	**Not fully rotated into locked position**	**Make sure cartridge holder is twisted counter clockwise until it stops**
Glass cartridge breakage	**Cartridge installed at improper angle**	**Always install cartridge in perpendicular position**
	Cartridge not pierced	**See pg 6 for proper puncture technique**
	Blocked needle or disposable	**Replace needle and/or disposable**

Announcements	Cause
"System Error" + 3 tones	Memory data corruption (Main code, Boot Loader, EEPROM read/write fail) or Power Supply Fault
"Plunger error" + 3 tones	Platform/motor failure (failed to home, stuck plunger). Used in manufacturing to indicate adjustment failure of platform
"Cartridge Error" + 3 tones	This alarm is active only if auto-cartridge is enabled. Indicates cartridge breakage/disconnect during plunger movement or cartridge attached while clean mode is activated.
"Relocate" or "Overpressure" over tone or tone only	Occlusion of tubing or overpressure condition due to blocked needed. Stuck plunger.

If problems persist contact your local distributor (international) or Milestone Scientific (USA) 800-862-1125 or 973-535-2717 for further assistance and instrument repairs. Do not attempt to repair the instrument yourself.

ADVANCED OPERATION

DYNAMIC PRESSURE SENSING (DPS) TECHNOLOGY

DPS technology is unique in that it allows a clinician to easily and accurately identify specific tissue types, at the needle position, based on tissue compliance. The ability to accurately identify specific tissue types based on real-time measurements of tissue resistance (i.e. tissue compliance, interstitial tissue pressure) is an important and critical aspect of using dynamic pressure sensing (DPS) technology. Pressure measurement of different tissue-density type is related to the physical compliance of a specific tissue during fluid injection.

Dr. Mark Hochman introduced a fundamental change to drug delivery systems by developing dynamic pressure sensing (**DPS**) technology with Milestone Scientific, Inc. thus enabling fluid-pressure and flow rate at the needle-tip to be precisely controlled and monitored in real-time during all phases of injection process. This pressure regulated computer-controlled local anesthetic delivery system (Pressure-CCLADS) represents a second generation device. Applying this new concept to dental injections enables the clinician to perform an easier, faster and more reliable dental injection technique. Importantly, it empowers the dentist to use the STA-Intraligamentary injection as a predictable primary injection technique.

The STA (Single Tooth Anesthesia) System is the only computer-controlled dental local anesthetic delivery system in the world to provide real-time DPS technology . At the core of the STA (Single Tooth Anesthesia) System lies an electro-mechanical motor regulated by a central microprocessor instrument (CPU) functioning in concert with a force/pressure transducer. A series of force/pressure transducers detect system resistances, allowing a mathematical algorithm to calculate instantaneous real-time measurements of the fluid “exit pressure”. The measured pressure data becomes a feedback signal which is then converted into an audible sound, as well as a visual display so that the user is continuously aware of the tissue density encountered. The concept of real-time dynamic pressure sensing and displaying is unique to this device and technology.

ADVANCED OPERATION

DYNAMICS OF THE INJECTION[1]

1. COMPONENTS OF THE INJECTION

The STA (Single Tooth Anesthesia) System offers both physical and psychological advantages over conventional syringe technology. There are three (3) physical components to any injection which play a role in what the patient may experience during the injection process; 1. The initial penetration of the needle into tissue, 2. The advancement of the needle through the tissue and, 3. The deposition of anesthetic fluid in the tissue. The delicate pen-like Wand® STA handpiece allows the operator to gently penetrate the mucosa and then direct the needle with unparalleled accuracy and precision. This promotes the accurate placement of the needle and deposition of anesthetic to achieve profound anesthesia. The psychological advantage of the Wand® STA handpiece is that it does not resemble a syringe and is not threatening in appearance. If anticipatory anxiety is reduced and patient confidence is increased, the entire injection experience is likely to be a more positive one for the practitioner and the patient.

2. MICROPROCESSOR CONTROLLED FLOW RATES

Many patients believe that the needle insertion is what causes discomfort when, in fact, most of the pain is caused by the flow of the anesthetic. When injected too quickly, traditional anesthetics create a burning sensation. Experts in anesthesia agree that a controlled *ControlFlo* rate of injection is ideal[2]. The STA (Single Tooth Anesthesia) System, when set on the normal mode, uses *ControlFlo* and *RapidFlo*, which automatically delivers optimal flow rates, regardless of tissue density. These patented controlled flow rates result in an injection experience that is typically below the threshold of pain.

3. SLOW NEEDLE ADVANCEMENT CREATES ANESTHETIC PATHWAY

It is speculated that during needle insertion, a continuous positive solution pressure delivers an anesthetic drip that can precede the needle path. This anesthetic pathway is believed to assist in virtually eliminating discomfort as the needle penetrates through the tissue. STA injections often result in faster onset of anesthesia and a much more comfortable experience due to the anesthetic pathway. Advance the needle *very slowly.* To effectively create an anesthetic path it is necessary to pause (approx. 4 beeps) every 1 mm of advancement. The needle is advanced approximately 1 mm using active rotation, (see Rotation Needle Insertion, Section 4), pause for anesthetic flow, and then continue advancement. Rapid advancement of the needle will defeat the advantage of the anesthetic pathway.

[1] Hochman M., Friedman M. Technique Article: Injection Dynamics for a Comfortable Palatal Injection. In Review
[2] Malamed SF, Handbook of Local Anesthesia. Fourth Edition, Mosby, St. Louis, MO. ppg. 140-141

ADVANCED OPERATION

4. Hand Control and Rotational Needle Insertion Methods

The most obvious difference between a syringe and the Wand® STA handpiece is the delicate manner in which the Wand® STA can be held and manipulated. Weighing only a few grams, the ultra-light handpiece promotes precise movements and unsurpassed tactile feedback. Unlike a syringe, the Wand® STA handpiece needle can be rotated between the thumb and forefingers, making possible new insertion methods. Always move the needle forward very slowly with the STA (Single Tooth Anesthesia) System activated on the slow flow rate to generate an anesthetic pathway. There are three (3) distinct needle insertion methods:

- **Slight Rotation for <u>insertion into mucosa</u>**
  Insert the needle with a deliberate rotation at the moment it enters the mucosa. This will enhance penetration by reducing the forward force necessary for puncturing the tissue. With a mono bevel needle, rotation brings the sharp needle surfaces into contact with a greater area of the tissue during the puncture and initial penetration. Once the needle is through the tissue surface, axial or bidirectional rotation can be performed to move the needle forward. Insure that all forward movement is slow while *ControlFlo* is activated.
- **Bidirectional rotation to prevent needle deflection (180º)**
  In certain injections, such as the inferior alveolar block, accurate targeting is intimately related to clinical success. Needle insertion that penetrates greater than 10 mm can cause needle deflection regardless of needle gauge. This is due to the forces acting upon the mono-bevel needle. As the needle is advanced through the tissue, the tip is deflected. A bidirectional rotation of 180º in either direction will cancel deflection and should markedly increase accuracy. Bidirectional rotation (180º right and left) is performed by rotating the needle back and forth between the thumb and forefinger. The rotation is maintained along the axis of the needle path until the site is reached. Insure that the Wand® STA handpiece is not distorted because this will reduce the efficiency of rotation. The rotation movement itself should be performed at a rate of about one second in either direction. The operator will find that the rotational movement will also promote needle penetration without a conscious effort to move the needle forward. When mastered, this technique should greatly reduce anesthesia onset time and missed blocks.
- **Axial Rotation for insertion into palatal tissue (45º)**[1]
  This needle movement has the effect of bringing the sharp edges of the mono bevel needle into contact with the entire penetration site. It is particularly effective in the dense connective tissue of the palate and should be used in conjunction with the pre-puncture technique described on page 34. Axial rotation (45º right and left) is performed by rotating the needle back and forth between the thumb and forefinger.

The rotation is maintained along the axis of the needle path until bone is reached. Gently rotate the needle and move forward about 1 mm, stop for 4 seconds then proceed forward. This allows the anesthetic pathway to form. The rotation movement itself should be performed at a rate of about one second in either direction. The operator will find that the rotational movement will promote needle penetration without a conscious effort to move the needle forward.

SPECIAL NOTE ON NEEDLE DEFLECTION AND ROTATIONAL TECHNIQUE

Needle deflection has long been recognized as altering the straight path of needle insertion. This can negatively impact the accuracy and predictability of the inferior alveolar block injection resulting in "missed blocks" and inadequate mandibular anesthesia. This may be due to the fact that, when using a traditional syringe, the insertion of the needle is linear, making it subject to deflection forces (Diagram A).

New Bidirectional Rotational Insertion

Since the Wand® STA disposable handpiece is held in a pen-like grasp, it can be rotated continuously during insertion. A recent investigation has demonstrated that a bidirectional rotational insertion technique (Diagram B) will alter the vector forces responsible for needle deflection, regardless of the needle gauge[3]. These findings have numerous clinical implications, the most obvious of which is accurate needle tracking to the target site.

Needle Rotation and Force Reduction

Needle rotation also assists the cutting efficiency of the needle, helping to reduce the force needed to move the needle forward, so insertion is easier and smoother. In force tests using a digital scale, the force of the needle without rotation registers over 70 grams. With rotation of the needle, the force is dramatically reduced to just over 30 grams. This force reduction is very important in dense palatal tissue to achieve a comfortable injection. Also, with less force needed for penetration, the handpiece can be held with a light, delicate touch that maximizes tactile feel and control.

Benefits for the Practitioner

Potential benefits of the technique include:

1. Fewer "missed" mandibular block injections[3]
2. Fewer re-injections of anesthetic.
3. More rapid onset of local anesthesia.
4. Reduced volume of anesthetic necessary to achieve anesthesia.
5. Reduced post-operative discomfort (e.g. trismus) from fewer injections

[3] In vitro study of needle deflection: A linear insertion technique versus a bidirectional rotation insertion technique; Hochman, Mark N., DDS; Friedman, Mark J., DDS; Quintessence Int. 2000:30:33-39

5. Pre-Puncture Technique[4] for Palatal Injections

The palatal tissue is an area that requires careful attention to insure the most comfortable injection experience. The pre-puncture is a method that should significantly reduce the sensation of needle penetration. It relies on the torque of the STA motor to generate a high fluid pressure at low volume. This literally forces the anesthetic into the tissue prior to the actual needle penetration. The technique is as follows:

- Place the needle bevel against the palate, but do not puncture
- Place a sterile cotton tip applicator on the back of the bevel and apply and apply pressure (a).
- Activate the STA (Single Anesthesia) System on *ControlFlo* for 8 - 10 beeps to force anesthetic into the tissue
- Continue to apply pressure from the applicator and slowly start bi-axial rotation
- The pressure from the cotton tip applicator is used to deliver pressure anesthesia
- Continue axial rotation for 2 beeps moving forward 1-2 mm, followed by a brief pause for 4 beeps (b)
- Repeat previous step of rotation, forward movement, pause, until contact with bone is made.
- Once bone is reached stop axial rotation, but continue the *ControlFlo* flow rate
- Use the cotton tip applicator to catch drips as needle is withdrawn

(a)

(b)

[4] Hochman M, Friedman M. Technique Article: Injection Dynamics For a Comfortable Palatal Injection. Manuscript in Review

6. New Injection Dynamics with the STA (Single Tooth Anesthesia) System

Timing the exact moment that a drop of anesthetic is going to be expressed from the Wand® STA handpiece takes some practice. It is recommended that a cotton tip applicator be placed close to the site of injection to absorb any anesthetic solution which is expressed from the needle prior to penetration into the tissue and when the needle is removed from the tissue.

The *ControlFlo* (slow) rate is used during the initial stage of all injections. Maintaining the *ControlFlo* anesthetic drip during careful, slow penetration of the needle helps to create an anesthetic path within the tissue. This should be done even if penetration is only a few millimeters. In denser tissues such as the palate or periodontal ligament space, the ControlFlo rate of injection should be maintained through the entire injection process. Other injections such as the inferior alveolar nerve block or maxillary mucobuccal fold infiltration are initiated with a slow penetration and *ControlFlo* rate. Once the needle reaches the target landmark, aspiration is initiated and if negative, the faster *RapidFlo* or *TurboFlo* rate of injection can be employed. Aspiration can be repeated at any time during the injection by releasing pressure from the foot control.

CLINICAL TECHNIQUES

The STA (Single Tooth Anesthesia) System is capable of performing all the traditional injections that are routinely performed to achieve effective local anesthesia in dentistry. The distinction is that these dental injections can now be performed more comfortably and easier for both the patient as well as the operator when administered with the STA (Single tooth anesthesia) System.

The STA (Single Tooth Anesthesia) System enables you to perform several new dental injection techniques that were developed in conjunction with this technology. The AMSA, P-ASA and STA-Intraligamentary injections are unique dental injections in that they require precise flow-rates and pressure to safely and properly perform these injections. Each of these injections can be used effectively as primary dental injection when treating your patients.

CLINICAL TECHNIQUES
STA Intraligamentary

The STA-Intraligamentary injection represents an effective primary dental injection for single tooth anesthesia. It provides a level of safety, comfort and effectiveness previously unattainable. The STA-Intraligamentary injection and STA (Single tooth Anesthesia) System offers the clinician three distinct benefits that cannot be achieved using the standard dental syringe, the pistol-grip high-pressure syringe, or other CCLADS systems:

1. An objective means to determine tissue compliance and thereby determine the tissue type into which the needle is inserted.
2. Objective, continuous, real-time pressure feedback data ensuring that the prescribed moderate pressure range is maintained within the injected tissues.
3. Objective, real-time information as to the occlusion of a needle and/or the loss of pressure resulting from intra-oral anesthetic solution leakage.

The STA (single Tooth Anesthesia) System with DPS technology is the only computer-controlled local anesthetic delivery system with the ability to provide important clinical feedback in a real-time fashion, thus allowing adjustments and confirmations to be made as determined by the clinician. This sophisticated technology simplifies the process of the intraligamentary injection by providing clinicians with a new, interactive injection system.

Review of the STA-Intraligamentary Injection Technique:

1. Verify the instrument is set to “STA-Mode”
2. Perform the aspiration pre-test (as described in the instructions).
3. Initiate the *ControlFlo* flow rate, note that after approximately 3 seconds you will hear the word “CRUISE” spoken. You may elect to use cruise-control.
4. Gently and slowly advance the needle within the sulcus, as if it was a periodontal probe. Begin injection at distal site followed by mesial.
5. Use a finger-rest to control the movement to carefully control and stabilize all needle movements.
6. As the needle is introduced through the tissues, the STA (Single Tooth Anesthesia) System provides continuous audible and visual feedback to assist the clinician.
7. As the pressure is increases the visual pressure sensing scale (i.e. gauge) on the front of the instrument the L.E.D. lights will change from – orange to yellow to green.
8. As the pressure increases the auditory feedback comprised of a series of ascending tones will be heard.

NOTE: It is not unusually to have to reposition the needle multiple times to identify the optimal needle-to-ligament position. This “searching” is guided by real-time dynamic pressure sensing feedback and is what allows a clinician to develop a high degree of predictability and accuracy when performing this injection.

9. Once the optimal position within the intraligamentary tissue has been identified the clinician will initially hear the letters “PDL” spoken followed by a repeated tone, indicating that the correct needle position has been achieved. In addition, the visual pressure sensing scale will illuminate the green LED’s.
10. The user should deposit the appropriate amount of anesthetic solution once positioned within the intraligamentary tissues.

NOTE: An “over-pressure” condition is when pressures exceed the maximum pressure programmed in the instrument. The STA (Single Tooth anesthesia) System will sound an auditory and visual alert and the instrument will stop. The clinician can then restart the injection. It might be necessary to re-position or move the needle to a new location**. It is not uncommon for an “relocate” or “over-pressure” condition to occur, this emphasizes an importance of being able to monitor real-time pressure with DPS technology.**

Drug Selection:

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The following information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

When using 2% Xylocaine Hydrochloride 1:100,000 Epinephrine or other local anesthetics formulated with a 2% concentration the following recommendations are made:

- A drug volume of 0.9 ml is recommended for single rooted teeth.
- A drug volume of 1.8 ml is recommended for multi-rooted teeth.

When using 4% Articaine Hydrochloride or other local anesthetics formulated with a 4% concentration the following recommendations are made. **NOTE:** it is recommended when using 4% Articaine hydrochloride that only a 1:200,000 vasoconstrictor concentration be used:

- A drug volume of 0.5 ml is recommended for single rooted teeth.
- A drug volume of 0.9 ml is recommended for multi-rooted teeth.
- The use of 2% local anesthetics containing a vasoconstrictor concentration of 1:50,000 parts is not recommended for administration of an intraligamentary injection.
- The use of 4% local anesthetics containing a vasoconstrictor concentration of 1:100,000 parts is not recommended for administration of an intraligamentary injection and palatal injections (i.e. AMSA and P-ASA).

Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. As noted above if you elect to use 4% concentrated anesthetic drug, use ½ the normally recommended and use extreme caution.

STA-Intraligamentary indications and contraindications:
The indicated use of the STA-Intraligamentary injection is as a primary injection for patients receiving dental care. A thorough medical history and dental history should be routinely taken on all patients. Patients should be in general good health. The clinicians are advised to rely on their own judgment and refer to standard dental anesthesia textbooks for accepted standards of care regarding this subject matter.

Contra-indication: Intraligamentary injections are contraindicated in patients with active periodontal disease.

NOTE: It is important to note that multiple clinical studies have been published and presented using computer-controlled local anesthesia systems for pediatric patients. The scientific data supports and encourages the use of this device to perform the intraligamentary injection specifically for the pediatric patient.

1. Allen KD, Larzelere RE, Hutfless S, Beiraghi S. Comparison of a computerized anesthesia device with a traditional syringe in preschool children. *Pediatr Dent.* 2002;24:315-320.
2. Ram D, Peretz B. Assessing the pain reaction of children receiving periodontal ligament anesthesia using a computerized device (Wand). *J Clin Pediatr Dent.* 2003;27:247-250.
3. Ashkenazi M, Blumer S, Ilana E. Effectiveness of computerized delivery of intrasulcular anesthetic in primary molars. *JADA.* 2005;136:1418-1425.
4. Versloot J, Veerkamp JSJ, Hoogstraten J. Computerized anesthesia delivery system vs. traditional syringe: comparing pain and pain-related behavior in children. *Eur J Oral Sci.* 2005;113:488-493.
5. Öztas N. Ulusu T. Bodur H. Dogan C. The Wand in pulp therapy : An alternative to inferior alveolar nerve block. Quint. International. 2005;36:(7)559-564.
6. Nicholson JW, Berry TG, Summitt JB, Yuan CH, Witten TM. Pain perception and utility: A comparison of the syringe and computerized local injection techniques. Gen Dent. 2001;167-172.

Post-operative Complications:

1. The PDL ligament tissue can be traumatized by mechanical injury from needle manipulation. **Avoid excessive hand-force on the needle.**
2. Delivery of improper amounts of anesthetic solution can result in excessive fluid volume to the dental papilla and/or periodontal ligament. **Excessive anesthetic volumes can cause tissue damage.**
3. The improper selection of dental anesthetic drug can cause adverse tissue reaction. **Refer to an appropriate reference source for guidance and recommendations.**

Anterior Middle Superior Alveolar (AMSA) Injection Technique[5]

The AMSA is an exciting addition to local anesthesia techniques. It will allow the operator to achieve pulpal anesthesia from the maxillary central incisor through the second premolar including the palatal tissue and mucoperiosteum from a single needle penetration. The recommended dosage is from 3/4 to 1 cartridge of anesthetic and the expected duration of anesthesia is approximately 60 minutes. A bilateral AMSA anesthetizes 10 maxillary teeth extending from the second premolar to the opposite second premolar and the associated palatal tissue from just 1 1/2 to 2 cartridges of anesthetic. The lips, face and muscles of expression are not anesthetized with the AMSA resulting in greater patient comfort operatively and post operatively. In addition, esthetic smile-line assessments are not hampered by facial distortion associated with traditional mucobuccal fold injections. To enhance buccal soft tissue anesthesia a small volume of anesthetic is administered at the muccal gingival junction.

The AMSA is easily administered, requiring up to 4 minutes to complete. Anesthesia is achieved within approximately 5 - 7 minutes of injection. The patient should be prepared for the extra time required to administer an AMSA and advised they will likely experience only a minor sensation from the injection. They will appreciate the lack of numbness to the face and lips.

A 30 gauge extra-short needle is recommended. It is inserted in a position that bisects the premolars and is approximately halfway between the mid-palatine suture and the free gingival margin. On patients with either a flat or excessively high palatal vault, the landmark is adjusted closer to the mid-line. If desired, topical anesthetic may be applied. The needle bevel is initially oriented parallel to the palatal tissue. A sterile cotton tip applicator is employed to apply pressure on the needle to “seal” the bevel to the tissue for the “pre-puncture” phase of the insertion. (see pre-puncture section) The foot control is depressed slightly to activate the *ControlFlo* flow rate for 8 - 10beeps prior to slow needle insertion. The cotton tip will help catch any anesthetic drips that occur before the bevel is completely within the tissue. The needle movements are extremely slow and gentle during penetration while the *ControlFlo* flow rate is maintained. The needle is reoriented to a 45º angle as it is advanced until it contacts the bone.

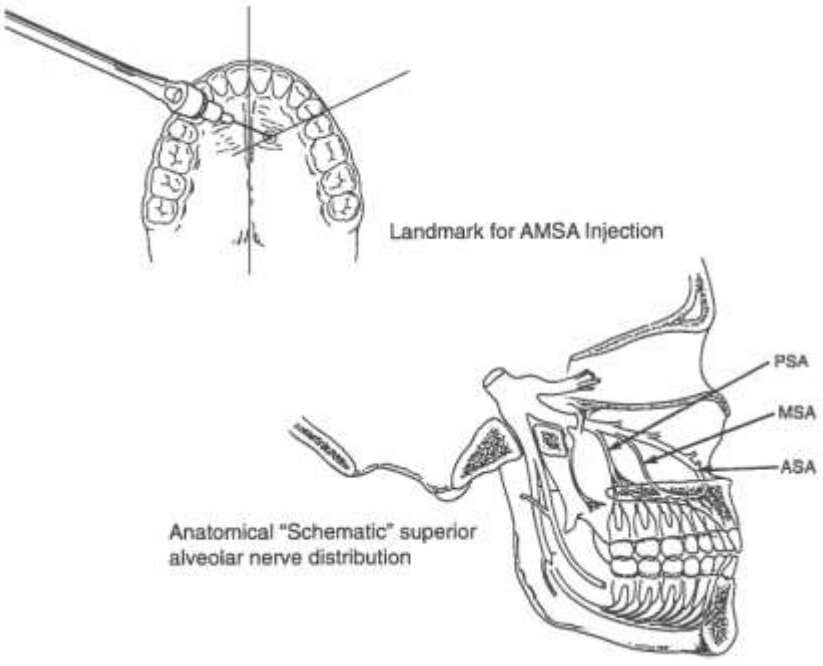
[5] The AMSA injection: A new concept for local anesthesia of maxillary teeth using a computer-controlled injection system; Friedman, Mark J., DDS; Hochman, Mark N., DDS; Quintessence Int. 1998: 29:297-303.

Perform aspiration. Maintain contact on bone and deliver the required dosage of 3/4 to 1 cartridge. Significant blanching of the palate will be observed (with anesthetics containing vasopressor) and care should be taken upon needle removal to reduce anesthetic solution from dripping down the posterior palate.

Note: It is critical that only the *ControlFlo* rate be used for this injection. Using the fast rate of flow may cause excessive ischemia and tissue damage. It is recommended that anesthetic containing vasopressor concentration of 1:100,000 or 1:200,000 be used. Caution should be exercised with 1:50,000 concentration of vasopressor. Excessive ischemia can result in soft tissue damage.

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The previous information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

⚠ **Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. If you elect to use 4% concentrated anesthetic drug, use ½ the normally recommended and use extreme caution.**



REVIEW OF THE AMSA INJECTION TECHNIQUE

1. Prepare the patient for a longer injection experience.
2. Place topical anesthetic on the palatal tissue if desired.
3. Orient a 30 gauge extra-short needle, bevel parallel to the palatal tissue at the landmark which bisects the premolars and is midway between the free gingival margin and the mid palatine suture.
4. Place a sterile cotton tip applicator to absorb any anesthetic drip prior to needle penetration.
5. Perform pre-puncture technique.
6. Rotate needle slightly upon entering tissue and during movement to final site.
7. Initiate the ControlFlo flow rate at the moment that the needle enters the palatal tissue and maintain this rate continuously. Reorient needle to 45º and advance the needle very slowly until it contacts bone.
8. Perform aspiration.
9. Cruise control can be activated if desired.
10. Continue to inject until approx. 3/4 to 1 full cartridge (if using 2% concentration) has been deposited.
11. Remove the needle slowly and try to avoid any excess anesthetic dripping.
12. Repeat on the contralateral side if required.

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The provided information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. If you elect to use 4% concentrated anesthetic drug, use ½ the normally recommended and use extreme caution.

The Palatal Anterior Superior Alveolar (P-ASA)[6]

The P-ASA is another modified injection for the anterior maxilla. It will allow the operator to achieve bilateral anesthesia of the maxillary incisors and usually the canines from a single needle penetration. In addition to pulpal anesthesia, profound palatal anesthesia of the gingiva and mucoperiosteum as well as moderate anesthesia of the facial gingiva associated with the teeth is achieved. The recommended dosage is from 3/4 to 1 cartridge of anesthetic (if using 2%) with the expected duration of anesthesia of approximately 60 - 90 minutes. Of significant benefit is that the lips, face and muscles of expression are not anesthetized with the P-ASA. This results in greater patient comfort operatively and post operatively. In addition, esthetic smile-line assessments are not hampered by facial distortion associated with traditional mucobuccal fold injections in this region.

The P-ASA is easily administered, requiring from 2 - 4 minutes to complete. Anesthesia is achieved within approximately 2 minutes of injection. The patient should be prepared for the extra time required to administer the P-ASA and advised they will likely experience only a minor sensation during the injection. They will appreciate the lack of numbness to the face and lips.

A 30 gauge extra-short needle is recommended. It is inserted adjacent to the incisive papilla. If desired, topical anesthetic may be applied. The needle bevel is initially oriented as parallel to the palatal tissue as possible. A sterile cotton tip applicator is employed to apply pressure on the needle to “seal” the bevel to the tissue for the “pre-puncture” phase of the insertion. (see pre-puncture section) The foot control is depressed slightly to activate the *ControlFlo* flow rate for 8 - 10 beeps prior to slow needle insertion. The cotton tip will help catch any anesthetic drips that occur before the bevel is completely within the tissue. The needle movements are extremely slow and gentle during penetration while the *ControlFlo* flow rate is maintained. After penetration into the papilla, insertion is continued until significant blanching of the papilla is observed. The needle is then reoriented to gain entrance into the nasopalatine canal and advanced very slowly no more than 1 cm (approximately the depth of a 1/2 inch needle). Maintain contact on bony wall of the canal and then aspirate. Deliver the required dosage of 3/4 to 1[7] cartridge. Significant blanching of the palate tissue and often the facial tissue will be observed (with anesthetics containing vasopressor). Care should be taken upon needle removal to reduce anesthetic solution dripping down the palate. Do not advance the needle beyond 1/2 inch (1 cm) since the floor of the nose can be penetrated which may lead to an infection.

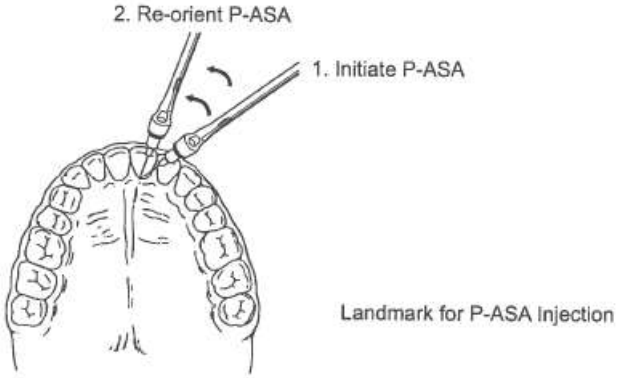
[6] Friedman MJ, Hochman MN. P-ASA Block Injection: A New Palatal Technique to Anesthetize Maxillary Anterior Teeth, Journal of Esthetic Dentistry, 1999, Vol. 11, Number 2.

[7] Dosage requirement for adequate anesthesia and duration may vary from one patient to another.

CLINICAL TECHNIQUES
P-ASA

Note: It is critical that only the *ControlFlo* rate be used for this injection. Using the fast rate of flow may cause excessive ischemia and tissue damage. It is recommended that anesthetic containing vasopressor concentration of 1:100,000 or 1:200,000 are used. Caution should be exercised with 1:50,000 concentration of vasopressor. Excessive ischemia can result in soft tissue damage.

Figure 15



REVIEW OF THE P-ASA INJECTION TECHNIQUE

1. Prepare the patient for a long injection experience.
2. Place topical anesthetic on the incisive papilla if desired.
3. Orient a 30 gauge extra-short needle in the groove just lateral to the incisive papilla.
4. Use a sterile cotton tip applicator for the pre-puncture technique.
5. Initiate the *ControlFlo* flow rate and maintain this rate throughout the injection.
6. After 8 - 10 beeps initiate axial rotation and VERY SLOW forward movement but continue *ControlFlo* flow rate.
7. Once the needle bevel enters below the papilla, pause movement for 5 - 6 seconds.
8. After papilla is blanched, re-orient the needle vertically to gain entrance to the nasopalatine canal with slow axial rotation.
9. When the needle is in the canal and contacting the inner bony wall, stop movement and aspirate. DO NOT EXCEED 1 cm (length of 1/2 inch needle) penetration into the canal.
10. If aspiration is negative, maintain position and deliver 3/4-1 cartridge of anesthetic (If using 2% solution) at the *ControlFlo* rate.
11. Cruise control can be activated if desired.
12. Remove needle slowly to avoid excess dripping into the mouth.

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The previous information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. If you elect to use 4% concentrated anesthetic drug, use ½ the previously recommended and use extreme caution.

CLINICAL TECHNIQUES TRADITIONAL

Traditional Infiltration Technique

The STA (Single Tooth Anesthesia) System and the Wand® STA handpiece are ideally suited for the administration of traditional injections. A **Maxillary Mucobuccal Fold** infiltration is initiated with the *ControlFlo* rate – first position on the foot control. The needle is advanced slowly until it reaches the intended target site. Aspiration is initiated if required (release foot control pressure) and, if negative, the *RapidFlo*™ rate (second foot control position) can be initiated. A **Posterior Superior Alveolar Block** injection (PSA) can be performed in a similar manner. Palatal infiltration can also be performed consistently and comfortably with the STA (Single Tooth Anesthesia) System. However, it is critical that the ControlFlo flow rate be used exclusively. **Never use the *RapidFlo* or *TurboFlo* rate for palatal injections.**

Review of Traditional Maxillary Mucobuccal Fold Infiltration Technique:

1. Perform an aspiration pre-test (as described in the instructions).
2. Initiate the *ControlFlo* (first foot control position) flow rate.
3. Slight needle rotation at the moment of mucosa puncture facilitates penetration of the surface tissue.
4. Penetrate mucosa with a slow, gentle advancement of the needle to create an “anesthetic pathway”.
5. When the needle reaches the target site, aspiration can be initiated if required (release foot control). If using Cruise Control, tap the foot control to aspirate.
6. Aspiration is repeated until negative aspiration is observed.
7. When aspiration is negative, initiate the *RapidFlo* (second foot control position) flow rate.
8. Monitor the LED panel to determine the volume of anesthetic delivered.
9. When the cartridge is emptied (audio and visual signal), reload, purge and continue as required.
10. 2% Lidocaine HCL 1:100,000 epinephrine and a drug volume of ¾ to 1 cartridge is recommended for this procedure.

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The previous information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. If you elect to use 4% concentrated anesthetic drug, use ½ the previously recommended and use extreme caution.

CLINICAL TECHNIQUES
INFERIOR ALVEOLAR

Inferior Alveolar (Mandibular) Nerve Block

The most common approach to mandibular anesthesia is the Inferior Alveolar Nerve Block injection. The Wand® STA handpiece enables the operator to concentrate on accurate needle placement and provides unprecedented control and tactile feel during this injection. The rotational insertion technique described earlier reduces needle deflection and missed blocks and facilitates more rapid onset of anesthesia.

The aspiration mode should be enabled prior to initiating the injection. Topical anesthetic can be applied to the intended injection site. However, it may not be required to achieve a comfortable penetration. *ControlFlo* is initiated prior to needle penetration of the mucosa. Rotate the Wand® STA handpiece slightly at the commencement of the injection to reduce pressure required for needle penetration. Advance the needle slowly using a continuous rotation technique to reduce needle deflection to the intended target site. Initiate aspiration by releasing the foot control. If using Cruise Control, tap the foot control to aspirate. If positive, reposition the needle and resume the *ControlFlo* flow rate and repeat aspiration. If aspiration is negative either *RapidFlo* or *TurboFlo* rates can be initiated. For buccal anesthesia of the soft tissue and periosteum of the mandibular molars, administer a long buccal nerve block. Other mandibular injections can be performed in a similar manner (Mental, Incisive, Gow Gates, Vazirani-Akinosi and Long Buccal.)

Review of Traditional Inferior Alveolar (Mandibular) Block Technique:

1. Perform an aspiration pretest (as described earlier).
2. Initiate the *ControlFlo* (first foot control position) flow rate.
3. Penetrate the mucosa with a slow, gentle advancement of the needle to create an “anesthetic pathway”.
4. Slight needle rotation at the moment of mucosa puncture facilitates penetration.
5. Use needle rotation technique during entire insertion to reduce needle deflection.
6. When the needle reaches the target site, aspiration is initiated (release foot control or tap foot control if using Cruise Control).
7. If blood is observed in handpiece tubing, reposition and repeat aspiration
8. When aspiration is negative, initiate the *RapidFlo* (second foot control position) flow rate.
9. Monitor the LED panel to determine the volume of anesthetic delivered
10. When the cartridge is emptied (indicated by audio and visual signals), reload, purge and continue as required.
11. 2% Lidocaine HCL 1:100,000 epinephrine and a drug volume of ¾ to 1 cartridge is recommended for this procedure.

All traditional injections in the maxilla and the mandible are performed following the steps outlined above. When not required, the aspiration mode can be disabled by briefly depressing the aspirate mode button. Light will turn off.

CLINICAL TECHNIQUES
INFERIOR ALVEOLAR

It is the responsibility of each practitioner to identify, select and administer the proper drug volume for a given patient. The previous information serves as a suggestion and is not meant as definitive guidelines for any specific patient. Refer to an appropriate text book reference for guidance and recommendations pertaining to local anesthetic solutions and specific volumes.

Caution: Untoward reactions have been reported using 4% concentrated local anesthetics. If you elect to use 4% concentrated anesthetic drug, use ½ the previously recommended and use extreme caution.

ADDITIONAL INFORMATION

Warranty Information
FOR INTERNATIONAL WARRANTY CONSULT YOUR LOCAL DISTRIBUTOR
STA Computer Controlled Local Anesthetic Delivery System Limited Warranty
United States

The STA (Single Tooth Anesthesia) System is warranted for a period of one year from date of purchase against manufacturing defects in materials and workmanship, and any claims under this warranty must be made and received before the end of such one year period. Repairs or replacement will be made by Milestone Scientific or its authorized agents at the sole discretion of Milestone Scientific. This warranty shall be limited to replacement or repair of the instrument or its parts and shall not include any other claims, including but not limited to loss of profit, cost of removal or replacement or special, incidental, or consequential damages or other similar claims arising from the use of this product.

Damages to the product resulting from acts of God, faulty installation, misuse, tampering, accident, abuse, negligence, or unauthorized repairs or alterations unrelated to problems with materials and workmanship are not covered by this warranty.

Milestone Scientific specifically disclaims all other warranties, expressed or implied, including but not limited to any implied warranty of merchantability or fitness for a particular purpose.

This warranty gives you specific legal rights, and you may have other rights which may vary from state to state.

WARRANTY AND NON-WARRANTY SERVICE

Warranty and non-warranty service is to be handled through Milestone Scientific. If you are experiencing a problem, please call Milestone Scientific for technical support prior to returning the instrument. When returning please provide adequate and protective packaging. Include your name, address, phone number and a thorough description of the operating problem. After repairing or replacing this product Milestone Scientific will return it directly to you.

ADDITIONAL INFORMATION

Power Requirements

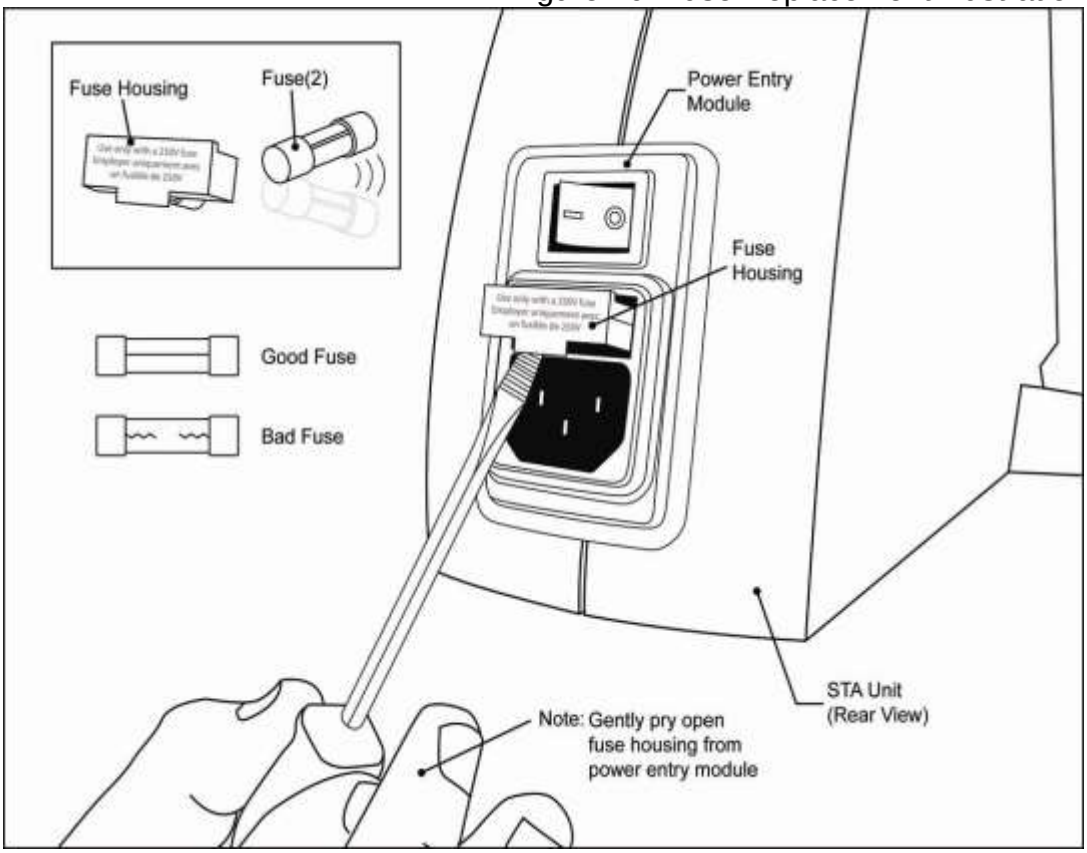
a. 110 – 120 VAC 50/60 Hz, .3A
i. Korea: 100-110V 50/60Hz. .3A

b. 200-240 VAC 50/60 Hz, .15A
i. Australia: 200-230V 50/60 Hz, .15A
ii. Korea: 200-220V 50/60 Hz, .15A

Fuse Replacement

Fuse Specifications: 0.5A 5 X 20 mm slo blo fuse
Manufacturer: Littlefuse
Part Number: 0218-500P

Figure 16 Fuse Replacement Illustration



The procedure below is to be followed when fuse replacement is required. Warning: remove all power to the STA (Single Tooth Anesthesia) System before proceeding.

1. Unplug and remove all power from the STA (Single Tooth Anesthesia) System
2. Carefully pry open the fuse housing from the power entry module as shown in the figure above.
3. Remove both fuses and evaluate them. If the fuses are determined to be “Bad” then replace them with a next to the power entry module located on the back of the instrument.
4. Carefully, replace fuse housing and snap into power entry module.

ADDITIONAL INFORMATION

Product Safety Information

The following is a brief description of the classifications which apply to this instrument including a detailed explanation of the nameplate label.

CE 0459	Indicates CE Classification
C UL US	Indicates UL Classification
	Identifies fuse location and type
	Attention, consult ACCOMPANYING DOCUMENTS
	Symbol indicating disposal of this product should be in accordance with WEEE Directive 1999/31/EC
	Indicates Applied parts Type Classification
	Warning, Consult ACCOMPANING DOCUMENTS
	Consult Instructions for use

This unit is considered a "continuous use" device and was tested in a worst case situation. 'Worst case' was defined as dispensing 10 consecutive cartridges of anesthetic with only the minimal amount of time required to replace each cartridge. In normal use the rate of dispensing cartridges should not exceed this limit without allowing the unit to stand idle for a minimum of 15 minutes.

ADDITIONAL INFORMATION

This instrument is defined as a Class IIA device per Rule 11 of the Medical Directive. The enclosure is suitable for an ordinary location. The function of this instrument defines it as Type BF. This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide. This instrument is a Class 1 earthed device.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential situation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

ADDITIONAL INFORMATION

Source for Further Reading

Computer Controlled Local Anesthesia Delivery System References

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